



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/900,220 07/24/97 MIAO

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FOLEY, HOAG & ELIOT, LLP  
PATENT GROUP  
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BOSTON MA 02109

HM12/0308

EXAMINER

BRANNOCK, M

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

03/08/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

## Advisory Action

Application No.  
**08/900,220**

Applicant(s)  
**Miao, N. et al.**

Examiner  
**Michael Brannock, Ph.D.**

Group Art Unit  
**1646**



THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on \_\_\_\_\_ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

**Applicant's response to the final rejection, filed on Feb 13, 2001 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
- ☒ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: see Attachment to Advisory Action

☒ Applicant's response has overcome the following rejection(s):

See Attachment to Advisory Action

- ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

See Attachment to Advisory Action

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: none

Claims objected to: 64, 66, and 68

Claims rejected: 35, 39, 40, 42, 43, 49, 52-54, 62, 63, 65, 67, 69, and 70

- ☐ The proposed drawing correction filed on \_\_\_\_\_ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☒ Other withdrawn claims are still pending

Art Unit: 1646

*Attachment to Advisory Action*

The shortened statutory period for reply expires THREE MONTHS from the mailing date of the final rejection or as of the mailing date of this advisory action, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Any extension fee required pursuant to 37 CFR 1.17 will be calculated from the date that the shortened statutory period for reply expires as set forth above.

The amendment filed 2/13/01 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because:

The proposed amendment raises new issues that would require further consideration and/or search. Amended claim 35 raises issues under 35 USC 112, second paragraph, because it is unclear if the recited "N-terminal fragment thereof" is a fragment of "a polypeptide comprising a hedgehog amino acid sequence" or a fragment of "a hedgehog protein of SEQ ID NO: 17".

New claim 72 introduces a new limitation, an amino acid sequence of 23-198 of SEQ ID NO: 17, which would require additional searching and consideration. New claim 74 introduces the new limitation "a polypeptide consisting essentially of a hedgehog amino acid sequence", which would require additional searching and consideration.

Art Unit: 1646

The rejection of claims 35, 39, 40, 42, 43, 63, 65, 69 and 70 under 35 USC 112, first paragraph, as set forth in item 4 of Paper 28, and reiterated in item of 11 Paper 32, 1/11/01, regarding adequate written description and scope of enablement is maintained, however Applicant's proposed arguments in the response of 2/13/01, would have been found persuasive had the amendment been entered.

Claims 63 and 67 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al., Genome Res. 6(807-828)1996, for the reason set forth in item 8 of Paper 28. Applicant argues that the amendments put forth in Paper 35 overcome the rejection, because the claims now require that the proteins are not fragments other than the recited fragment of about 19 kD. This argument is not found persuasive because the claims require a naturally occurring desert hedgehog protein or an N-terminal fragment thereof.

The rejection of claims 49, 52, 53, 54, 62 under 35 U.S.C. 112, second paragraph, as set forth in item 15 Paper 32 is maintained but would be obviated by Applicant's proposed amendments.

The objections to claims 43 and 35, put forth in Paper 32 are maintained but would have been obviated by Applicant's proposed amendments.

Art Unit: 1646

*Conclusion*

Claims 1-34, 41, 47, 48, 55-61 and 71 are withdrawn from consideration

Claims 35, 39, 40, 42, 43, 49, 52-54, 62, 63, 65, 67, 69 and 70 are not allowable.

Claims 64, 66, and 68 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

March 6, 2001

*David R. Jones*  
*Primary Examiner*